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PATENT APPLICATION

ATTORNEY DOCKET NO. 10004227-9

IN THE
UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Ray L. PICKUP et al.

Confirmation No.: 4848

Application No.: 10/791,974

Examiner: Melanie Jo HAND

Filing Date: March 3, 2004

Group Art Unit: 3761

Title: CUTANEOUS ADMINISTRATION SYSTEM

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Commissioner For Patents
PO Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF APPEAL BRIEF

Transmitted herewith is the Appeal Brief in this application with respect to the Notice of Appeal filed on June 16, 2008.

☒ The fee for filing this Appeal Brief is $510.00 (37 CFR 41.20).

☒ No Additional Fee Required.

(complete (a) or (b) as applicable)

The proceedings herein are for a patent application and the provisions of 37 CFR 1.136(a) apply.

☐ (a) Applicant petitions for an extension of time under 37 CFR 1.136 (fees: 37 CFR 1.17(a)-(d)) for the total number of months checked below:

☐ 1st Month $120	☐ 2nd Month $460	☐ 3rd Month $1050	☐ 4th Month $1640

☐ The extension fee has already been filed in this application.

☒ (b) Applicant believes that no extension of time is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

Please charge to Deposit Account 08-2025 the sum of $ 510. At any time during the pendency of this application, please charge any fees required or credit any over payment to Deposit Account 08-2025 pursuant to 37 CFR 1.25. Additionally please charge any fees to Deposit Account 08-2025 under 37 CFR 1.16 through 1.21 inclusive, and any other sections in Title 37 of the Code of Federal Regulations that may regulate fees.

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Date of facsimile: August 18, 2008
Typed Name: Theresa Belland
Signature:

Respectfully submitted,
Ray L. PICKUP et al.
By

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Rev 10/07(AplBrief)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of		Dated:	August 18, 2008
Ray L. PICKUP et al.		HP Docket No.:	10004227-9
Serial No.: 10/791,974		Examiner:	Melanie Jo Hand
Filed:	March 3, 2004	Group Art Unit:	3761
For:	CUTANEOUS ADMINISTRATION SYSTEM	Confirmation No.:	4848

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

BRIEF OF APPELLANTS

This Brief is presented in opposition to the Examiner's rejection of claims 83-100, 102-109, 118-120, 123-128, 131-133, 136, 140, 141, 148-150, and 183-185 in the final Office action dated April 17, 2008 (hereinafter, "the final Office action").

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

The real party in interest is Hewlett-Packard Development Company, LP, a limited partnership established under the laws of the State of Texas and having a principal place of business at 20555 State Highway 249, Houston, Texas 77070, U.S.A. (hereinafter "HPDC"). HPDC is a Texas limited partnership and is a wholly-owned affiliate of Hewlett-Packard Company, a Delaware Corporation, headquartered in Palo Alto, California. The general or managing partner of HPDC is HPQ Holdings, LLC.

II. RELATED APPEALS AND INTERFERENCES

There are no known related appeals or interferences.

III. STATUS OF CLAIMS

The status of the claims is as follows:

Canceled – claims 1-82, 101, 110-117, 121, 122, 129, 130, 134, 135, 137-139, 142-147, and 151-182.

Rejected – claims 83-100, 102-109, 118-120, 123-128, 131-133, 136, 140, 141, 148-150, and 183-185.

The claims at issue in this appeal consist of all of the rejected claims listed above.

IV. STATUS OF AMENDMENTS

The claims were last amended in the Response to Office Action dated January 15, 2008. No amendments to the claims were proposed since their rejection in the final Office action dated April 17, 2008.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The following summary is a concise explanation of the subject matter defined in each of the two independent claims under appeal, namely, claim 83 and claim 91. The subject matter is exemplified by accompanying references to passages of the specification and to the drawings.

Independent claim 83 is directed to a method of administering a bioactive composition to a subject and involves use of a jet dispenser (e.g., see page 7, line 11, to page 9, line 9). A jet dispenser 200 is applied to a cutaneous surface of the subject (Figure 5; page 17, lines 8-16). The jet dispenser (200) comprises a container 208 holding the bioactive composition (Figure 5; page 17, lines 21-27; see also page 4, lines 14-27). The bioactive composition is dispensed in droplets 338, 406 from the dispenser through at least one orifice 218 toward the cutaneous surface (Figures 5-9; page 17, line 27, to page 18, line 1; page 18, lines 20-29). The bioactive composition becomes airborne upon leaving the at least one orifice and remains airborne until coming into contact with the cutaneous surface or a dermal patch thereon (page 4, lines 3-8; page 22, lines 20-26; Figure 8). The bioactive composition is retained in prolonged contact with the cutaneous surface (Figure 5; page 6, lines 11-15).

Independent claim 91 is directed to a method of administering a bioactive composition to a subject and involves use of an inkjet dispenser (e.g., see page 7, line 11, to page 9, line 9). A cutaneous patch 25 is applied to skin 24 of the subject (Figure 1; page 9, lines 12-20). The bioactive composition is dispensed from the inkjet dispenser by ejection through an orifice 218 spaced from and directly above a face of the patch

(Figures 5-9; page 17, line 27, to page 18, line 1; page 18, lines 20-29; page 22, lines 20-26).

Specific references to portions of the application are provided with the understanding that nonreferenced portions of the application also may be relevant. As such, it should be understood that the claims are not limited by the particular references made above, but rather are fully supported by the entirety of the disclosure.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellants request review of the following grounds of rejection on appeal:

1. Rejection of claims 83-85, 87-89, 91-95, 98, 99, 102, 105-107, 118, 123, 126, 131, 136, 140, 141, and 183-185 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,048,337 to Svedman ("Svedman").

2. Rejection of claims 86, 96, 97, 119, 120, 127, 128, and 148-150 under 35 U.S.C. § 103(a) as being unpatentable over Svedman.

3. Rejection of claims 90 and 100 under 35 U.S.C. § 103(a) as being unpatentable over Svedman in view of U.S. Patent No. 5,480,062 to Rogers et al. ("Rogers").

4. Rejection of claims 103 and 104 under 35 U.S.C. § 103(a) as being unpatentable over Svedman in view of U.S. Patent No. 6,325,475 to Hayes et al. ("Hayes").

5. Rejection of claims 108 and 109 under 35 U.S.C. § 103(a) as being unpatentable over Svedman in view of U.S. Patent No. 5,860,957 to Jacobsen et al. ("Jacobsen").

6. Rejection of claims 124, 125, 132, and 133 under 35 U.S.C. § 103(a) as being unpatentable over Svedman in view of U.S. Patent No. 5,179,947 to Meyerson et al. ("Meyerson").

To summarize, Appellants request review of the rejection of all pending claims under 35 U.S.C. § 102 or § 103 over Svedman alone or in combination with another reference.

VII. ARGUMENT

The Examiner has improperly rejected each of claims 83-100, 102-109, 118-120, 123-128, 131-133, 136, 140, 141, 148-150, and 183-185 under 35 U.S.C. § 102(b) or § 103(a) as being anticipated by or obvious over Svedman alone or in combination with another reference. When the claims are reviewed under the current standards for anticipation and obviousness as set forth by the Federal Courts and the Board of Patent Appeals and Interferences, the impropriety of the rejections becomes clear.

A. *The Legal Standard for Anticipation under 35 U.S.C. § 102*

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

B. *The Legal Standard for Obviousness under 35 U.S.C. § 103*

Obviousness is a question of law based on (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). "In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art." *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992). "If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled

to grant of the patent." *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

A number of circumstances preclude modification of a reference to establish *prima facie* obviousness. For example, if the reference teaches away from the proposed modification then there is no *prima facie* obviousness. *In re Young*, 927 F.2d 588, 18 USPQ2d 1089 (Fed. Cir. 1991). Furthermore, there is no *prima facie* obviousness if the proposed modification changes the principle of operation of the reference. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

C. ***Claims 83-90, 102-104, 108, 118-120, 123-125, 136, 140, 148, 149, and 183***

1. *Rejection of Claim 83*

Independent claim 83 is directed to a method, as follows:

> 83. A method of administering a bioactive composition to a subject, the method comprising:
>
> applying to a cutaneous surface of the subject a jet dispenser comprising a container holding the bioactive composition;
>
> dispensing the bioactive composition in droplets from the dispenser through at least one orifice toward the cutaneous surface such that the bioactive composition becomes airborne upon leaving the at least one orifice and remains airborne until coming into contact with the cutaneous surface or a dermal patch thereon; and
>
> retaining the bioactive composition in prolonged contact with the cutaneous surface.

In the final Office action, the Examiner rejected claim 83 as being anticipated by Svedman. However, as set forth above, a "claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a

single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Appellants submit that Svedman does not teach or suggest the airborne dispensing recited in claim 83, namely, "dispensing the bioactive composition in droplets from the dispenser through at least one orifice toward the cutaneous surface such that the bioactive composition becomes airborne upon leaving the at least one orifice and remains airborne until coming into contact with the cutaneous surface or a dermal patch thereon."

2. *Svedman Overview*

Svedman relates to a device for transdermal perfusion of fluids through de-epithelialized sites. For example, use of an exemplary device 1 for transdermal delivery of a liquid drug is illustrated in Figures 34-37 of Svedman, which are reproduced below to facilitate review.

Figure 34 illustrates device 1 in contact with a patient's skin 4. Device 1 has a base 3 and a rotatable portion 5 coupled to the base. Base 3 defines circular aperture 6, which is positioned over and bounds a circular area of skin 8. Rotatable portion 5 defines a cylindrical axis port 7 and a reservoir 11 containing a liquid drug. Access port 7 can be aligned with aperture 6 for application of suction via a suction cup 9, to raise a suction blister 17 in a chamber 16 defined by the suction cup. The suction blister is disclosed to be cut with a blade 18.

Figure 35 illustrates operation of the blade to cut the suction blister and suction cup 9. Cutting creates a de-epithelialized site that is centered at the base of chamber 16.

Figure 36 illustrates delivery of the liquid drug to the de-epithelialized site. The rotatable portion has been rotated to align an outlet port 22 of reservoir 11 with aperture 6 of base 3. As result, liquid drug moves from reservoir 11 into chamber 16 to fill the chamber, which floods the de-epithelialized site to induce transdermal uptake of the liquid drug.

Figure 37 illustrates isolation of chamber 16 from reservoir 11. The rotatable portion has been rotated further to position outlet port 22 out of alignment with chamber 16, such that both reservoir 11 and chamber 16 are sealed in fluid isolation from one another.

Significantly, in Figure 36 and throughout Svedman, the reference discloses flooding a de-epithelialized site with fluid. In other words, Svedman does not recognize any advantage in more targeted fluid delivery onto a de-epithelialized site. For example, Svedman does not teach or suggest controlled dispensing of fluid aliquots in order to restrict fluid contact to selected areas of the de-epithelialized site.

FIG. 34.

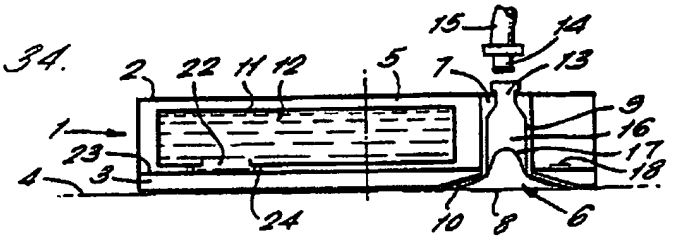


FIG. 35.

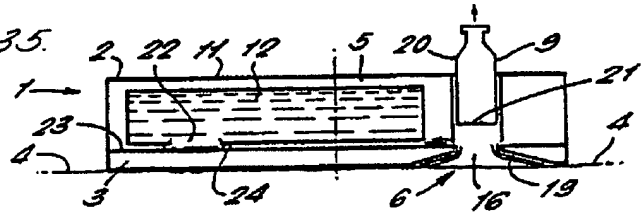


FIG. 36.

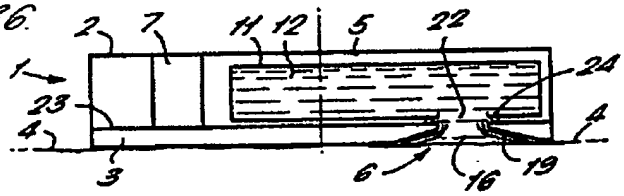
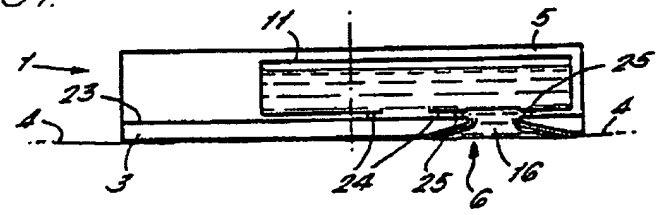


FIG. 37.



The Examiner cited Figure 78 and column 35, lines 46-63, of Svedman in rejecting claim 83. However, the cited text of Svedman relates to Figure 79, which is reproduced here to facilitate review.

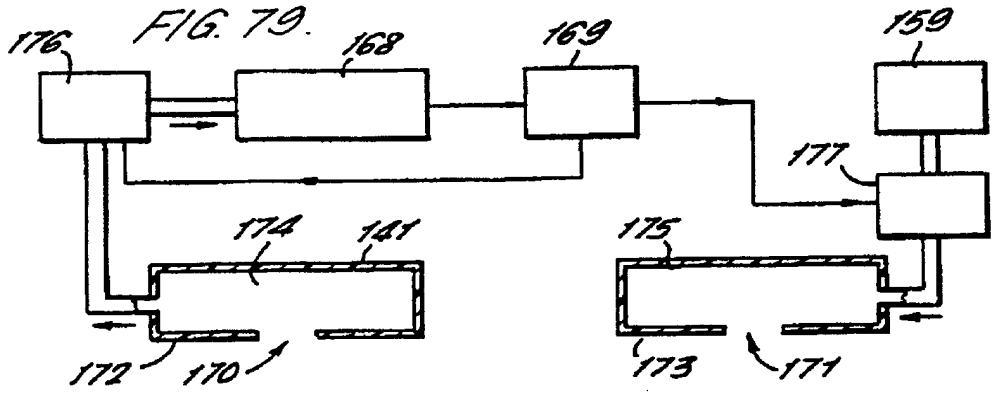


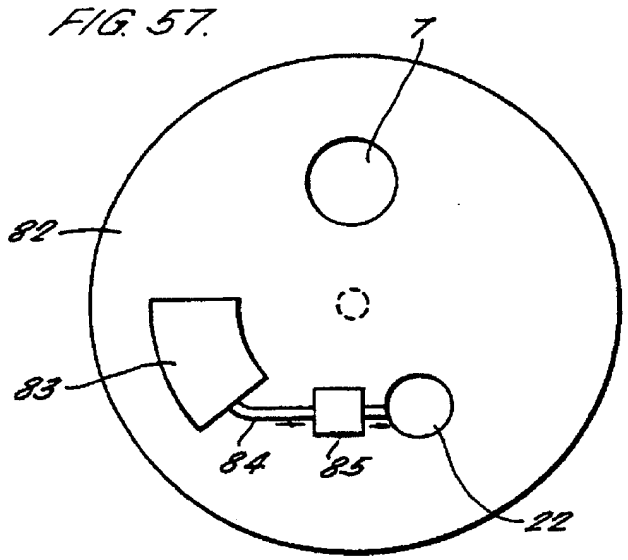
Figure 79 involves a device for use with two separate de-epithelialized sites 170 and 171. On the left, exudate is received from a de-epithelialized site 170 in a sample cell 174 defined by an enclosure 172 disposed over site 170. On the right, drug is delivered to a de-epithelialized site 171 via a sample cell 175 defined by an enclosure 173 disposed over site 171.

A pump 177 delivers metered quantities of a drug to sample cell 175 from a reservoir 159. Pump 177 is disclosed to be "a micro pump of the type normally used in bubble jet ink printers" and has an array of nozzles from which drug is dispensed.

However, the nozzles of pump 177 are not disclosed to be positioned in or contiguous to sample cell 175 for airborne dispensing of droplets to de-epithelialized site 171. Instead, as presented in Figure 79 above, pump 177 communicates with upstream reservoir 159 and sample cell 175 via conduits that convey the drug to and from pump 177. In particular, an upstream conduit extends from reservoir 159 to pump 177, and a downstream conduit extends from pump 177 to a side entry port of enclosure 173. The downstream conduit bends between pump 177 and enclosure 173.

Furthermore, de-epithelialized site 171 is not directly below the side entry port of enclosure 173, but is spaced laterally from the port by a bottom region of enclosure 173.

Appellants' interpretation of Figure 79 with respect to the downstream conduit is supported by another embodiment of Svedman's device, which is presented in Figure 57:



In this embodiment, a micro pump 85 impels liquid (e.g., a drug) from a reservoir 83 to an outlet port 22 via a capillary tube 84 extending upstream and downstream from micro pump 85 (col. 29, lines 39-47). Svedman thus discloses a downstream conduit having a very small internal diameter.

3. Svedman Does Not Anticipate Claim 83

Neither Svedman's device in Figure 79 nor the reference taken as a whole teaches or suggests the airborne dispensing of droplets recited in claim 83. In particular, pump 177 dispenses drug into a downstream conduit, for delivery of the drug from the

conduit to cell 175. Appellants contend that delivery of drug to the side of enclosure 173, the presence of a downstream conduit with a very small internal diameter, and particularly the sharply bent configuration of the downstream conduit, all demonstrate that Svedman intended the drug to flow from the downstream conduit into sample cell 175 and then to the patch of skin centered below the sample cell. In contrast, claim 83 recites "the bioactive composition becomes airborne upon leaving the at least one orifice and remains airborne until coming into contact with the cutaneous surface." No other part of Svedman teaches or suggests any airborne dispensing of droplets to a cutaneous target.

The Examiner asserted the following with respect to Svedman:

> [T]hroughout the disclosure, Svedman teaches that the technique for creating the de-epithelialized site for delivery of the composition comprises creating a blister and then removing the blister roof and replacing the roof with the orifice of the dispenser. The dispenser orifice is elevated with respect to the cutaneous surface and the base of the delivery site directly below is recessed with respect to the same cutaneous surface. Therefore, there is necessarily open space, or air, between the orifice where the droplets of composition exit and the subcutaneous surface defining the base of the de-epithelialized delivery site. The droplets enter this open space upon exiting the at least one orifice, becoming airborne in the open space between the plane of the orifices and the base of the delivery site, and remain airborne until they exit that space, i.e. the droplet comes in contact with the cutaneous surface of the delivery site. [Final Office Action, page 2, first paragraph.]

Despite the assertion by the Examiner, Svedman does not teach or suggest placement of a micro pump over a de-epithelialized site. Nevertheless, even if the micro pump and its downstream conduit were placed over the de-epithelialized site, airborne dispensing

to the de-epithelialized site would not be achieved because the downstream conduit would block airborne dispensing. However, the Examiner may be taking the position that the downstream conduit permits airborne travel of droplets from the micro pump nozzles to the chamber. Appellants strongly disagree. Svedman does not disclose any airborne droplets entering the downstream conduit. Furthermore, even if airborne droplets were to enter the downstream conduit, this conduit has a very small internal diameter and thus the droplets would lose their airborne status upon contact with the conduit wall or with liquid already deposited in the conduit. Svedman does not teach or suggest that the micro pump and downstream conduit are configured to allow the droplets to pass through the conduit without any contact. Furthermore, this configuration is inconsistent with the disclosure of Svedman because it would render the downstream conduit superfluous.

4. Claim 83 is Not Obvious over Svedman

Claim 83 was not rejected under Section 103 as being obvious over Svedman. Nevertheless, in making the rejection, under Section 102(b), the Examiner modified the disclosure of Svedman, and particularly the device of Figure 79, in an attempt to reach the claimed invention: (1) the downstream conduit that receives fluid from the micro pump apparently was omitted (or its function changed), and (2) the nozzles of the micro pump were re-positioned to aim ejected droplets at the cutaneous site. However, Appellants submit that even if the Examiner were to change the rejection of claim 82 to an obviousness rejection under Section 103(a) (instead of under Section 102(b)) over Svedman, there is no *prima facie* obviousness.

The Examiner relied on other parts of Svedman's disclosure (e.g., device 1 of Figures 34-37 reproduced above) to provide a teaching for placement of a dispenser orifice above a cutaneous surface, and then applied this placement of the dispenser orifice to the micro pump of Figure 79. However, in Svedman, a fluid drug is dispensed from a single orifice into a chamber abutting a cutaneous site. For example, with Svedman's micro pump, fluid from a reservoir is distributed to a plurality of nozzles but then is reunited in a single downstream conduit after ejection from the nozzles. Even if, only for the sake of argument, it would have been obvious to re-position the micro pump of Svedman as asserted by the Examiner, no portion of Svedman teaches or suggests use of the micro pump without the downstream conduit, which provides the single orifice from which fluid flows into the chamber.

It also would not have been obvious to modify Svedman as proposed by the Examiner because this modification changes the principle of operation of the reference. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Svedman discloses a device that causes fluid to flow into a chamber that abuts a de-epithelialized site. The modification proposed by the Examiner would cause fluid from the device to be dispensed into the chamber and onto the de-epithelialized site in an airborne manner. Appellants contend that changing the mechanism of fluid dispensing into the chamber, from flow-based dispensing out of a tube to airborne dispensing, amounts to a change in the principle of operation of Svedman's device. Furthermore, Appellants contend that the Examiner has relied on impermissible hindsight to change the principle of operation of Svedman based on Appellants' disclosure as a guide.

It also would not have been obvious to modify Svedman as proposed by the Examiner because Svedman *teaches away* from this modification. *In re Young*, 927 F.2d 588, 18 USPQ2d 1089 (Fed. Cir. 1991). In Svedman, even when fluid droplets are produced, as in the device of Figure 79, the fluid droplets are collected in a downstream conduit for flow-based delivery. Therefore, Svedman is teaching away from airborne dispensing to a cutaneous target by use of an additional structural element–the downstream conduit–to block airborne travel of droplets.

In more specific embodiments, airborne dispensing of droplets to a cutaneous target offers substantial advantages over the flow-based approach of Svedman. For example, a bioactive composition can be dispensed in a patterned or otherwise spatially restricted manner to a cutaneous target, which may permit two or more bioactive compositions to be dispensed to spaced sites on the same cutaneous target. Furthermore, the greater control over fluid placement provided by airborne dispensing may permit optical sensing or imaging of the dispensed bioactive composition in a manner not permitted by the approach of Svedman. Svedman blocks airborne dispensing of droplets and thus does not recognize any of the advantages afforded by the claimed invention.

5. Allowability of the Claims

In summary, Appellants submit that independent claim 83 is patentable over Svedman because the claim is neither anticipated by nor obvious over Svedman. Claim 83 thus should be allowed. Claims 84-89, 102, 118-120, 123, 136, 140, 148, 149, and 183, which depend directly or indirectly from claim 83 and were also rejected based only

on Svedman, also should be patentable for at least the same reasons set forth in support of the patentability of claim 83. In addition, claims 90, 103, 104, 108, 124, and 125, which depend directly or indirectly from claim 83, were rejected over a combination of Svedman with Rogers, Hayes, Jacobsen, or Meyerson. Each of these other claims also should be allowed for at least the same reasons as claim 83 because none of Rogers, Hayes, Jacobsen, and Meyerson cures the defects in Svedman described above.

D. Claims 91-100,105-107, 109, 126-128, 131-133, 141, 150, 184, and 185

1. Claim 91

Independent claim 91 is directed to a method, as follows:

> 91. A method of administering a bioactive composition to a subject, the method comprising:
>
> applying a cutaneous patch to skin of the subject; and
>
> dispensing the bioactive composition from an inkjet dispenser by ejection through an orifice spaced from and directly above a face of the patch.

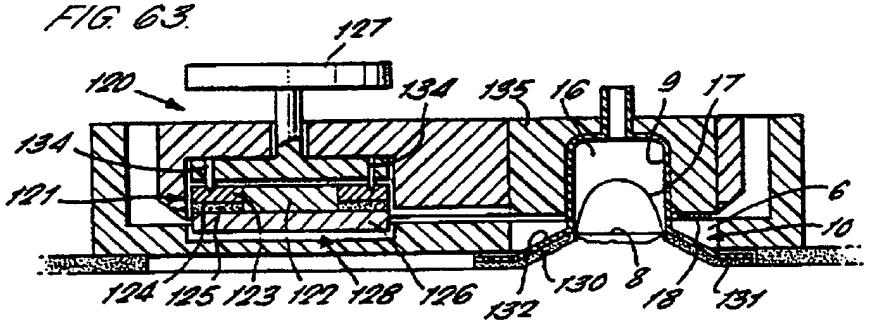
In the final Office action, the Examiner rejected claim 91 as being anticipated by Svedman. However, as set forth hereinabove, a "claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Appellants submit that Svedman does teach or suggest "dispensing the bioactive composition from an inkjet dispenser by ejection through an orifice spaced from and directly above a face of the patch."

2. *Svedman Disclosure on Patches*

Svedman discloses use of a patch in relation to Figures 63-71. Figures 63 and 69-71 are reproduced below to facilitate review.

Figure 63 depicts a patch applicator 120 that is operable to apply a patch 121 to a de-epithelialized area of skin 8. Patch 121 has a central disc-shaped element 122, a peripherally attached rigid support ring 123, and an adhesive layer 125.

FIG. 63.

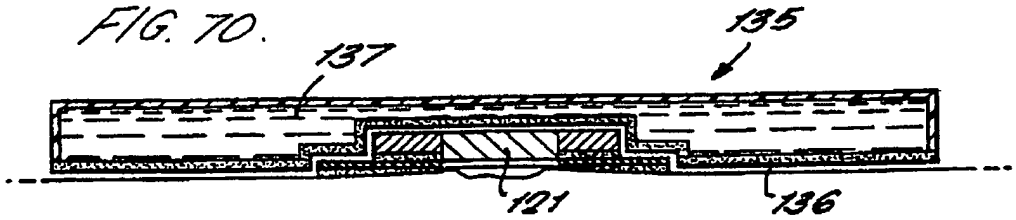


After de-epithelialization of the skin, the patch is engaged with the resulting de-epithelialized site and the patch applicator removed:

FIG. 69.

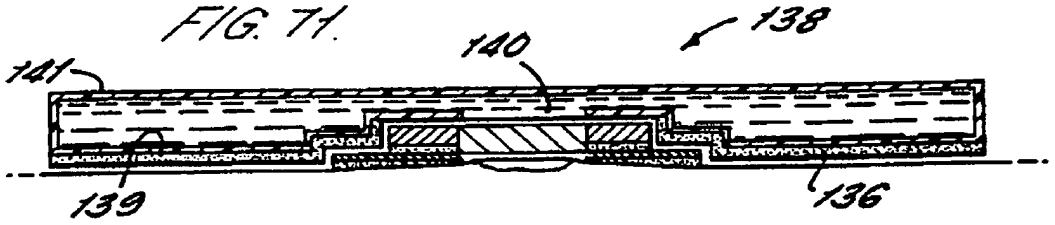
Patch 121 may be configured to be a self-contained means for dispensing a drug that diffuses out of the patch. Alternatively, as depicted below in Figure 70, a drug preparation 137 is disclosed to be carried by a conventional skin patch 135 that is applied over patch 121, for selective uptake of the drug through the de-epithelialized site under patch 121.

FIG. 70.



As another alternative, and as depicted below in Figure 71, a drug preparation is disclosed to be carried by a modified skin patch 138 that is applied over patch 121. The modified skin patch allows diffusion of the drug into patch 121 (and the underlying de-epithelialized site) via a central aperture 140 of modified skin patch 138.

FIG. 71.



3. *Svedman Does Not Anticipate Claim 91*

Svedman does not teach or suggest every element of claim 91. For example, Svedman does teach or suggest "dispensing the bioactive composition from an inkjet dispenser by ejection through an orifice spaced from and directly above a face of the patch," for at least two reasons. First, Svedman does not disclose any active mechanisms for dispensing a drug to a patch. For example, Svedman does not disclose use of any type of pump to actively dispense fluid above a patch and particularly does not disclose use of an inkjet dispenser for dispensing a bioactive composition above a patch, as recited in claim 91. Second, Svedman does not disclose ejection of a bioactive composition through an inkjet dispenser orifice that is spaced from and directly

above the face of any target, and particularly not the face of a patch. Instead, as explained above for claim 83, Svedman discloses a micro pump that dispenses a drug to a downstream conduit that is laterally offset from its cutaneous target. It also would not have been obvious to modify Svedman to achieve the claimed invention for at least the same reasons as those presented above for claim 83.

4. Allowability of the Claims

In summary, Appellants submit that independent claim 91 is patentable over Svedman and should be allowed. Claims 92-99, 105-107, 126-128, 131, 141, 150, 184, and 185, which depend directly or indirectly from claim 91 and were rejected based only on Svedman, also should be patentable for at least the same reasons as claim 91. In addition, claims 100, 109, 132, and 133, which depend directly or indirectly from claim 91, were rejected under Section 103 as being unpatentable over a combination of Svedman with Rogers, Jacobsen, or Meyerson. Each of claims 100, 109, 132, and 133 also should be patentable for at least the same reasons as claim 91 because none of Rogers, Jacobsen, or Meyerson cures the defects in Svedman described above.

E. Conclusion

For at least the reasons stated above, Appellants assert that all of the claims under appeal are patentable over Svedman alone or in combination with the other cited references. Accordingly, Appellants submit that the rejection of claims 83-100, 102-109, 118-120, 123-128, 131-133, 136, 140, 141, 148-150, and 183-185 under 35 U.S.C. § 102 and § 103 is improper and should be reversed.

VIII. CLAIMS APPENDIX

83. A method of administering a bioactive composition to a subject, the method comprising:

applying to a cutaneous surface of the subject a jet dispenser comprising a container holding the bioactive composition;

dispensing the bioactive composition in droplets from the dispenser through at least one orifice toward the cutaneous surface such that the bioactive composition becomes airborne upon leaving the at least one orifice and remains airborne until coming into contact with the cutaneous surface or a dermal patch thereon; and

retaining the bioactive composition in prolonged contact with the cutaneous surface.

84. A method according to claim 83, wherein retaining the bioactive composition in prolonged contact with the cutaneous surface comprises dispensing the bioactive composition on to a dermal patch that is retained on the cutaneous surface.

85. A method according to claim 84, wherein the dermal patch is an adhesive dermal patch that is applied to the cutaneous surface prior to dispensing the bioactive composition from the dispenser.

86. A method according to claim 85, wherein the dermal patch comprises a selectively removable cover that is removed prior to dispensing the bioactive composition into the patch, and is subsequently replaced on the patch to improve retention of the bioactive composition in the patch.

87. A method according to claim 83, wherein retaining the bioactive composition in prolonged contact with the cutaneous surface comprises providing a seal between the dispenser and cutaneous surface, to form a substantially sealed chamber between the dispenser and the cutaneous surface, and retaining the dispenser in prolonged contact with the seal.

88. A method according to claim 83, further comprising repeatedly dispensing the bioactive composition toward the cutaneous surface.

89. A method according to 88, further comprising resupplying the dispenser with the bioactive substance.

90. A method according to claim 89, wherein resupplying the dispenser comprises replacing a container in the dispenser.

91. A method of administering a bioactive composition to a subject, the method comprising:

applying a cutaneous patch to skin of the subject; and

dispensing the bioactive composition from an inkjet dispenser by ejection through an orifice spaced from and directly above a face of the patch.

92. A method according to claim 91, further comprising dispensing the bioactive composition to the patch at intervals to provide sustained dosages of the bioactive composition from the patch to the subject.

93. A method according to claim 92, wherein the intervals are preselected intervals.

94. A method according to claim 91 further comprising dispensing the bioactive composition from the dispenser to the patch when an amount of the bioactive composition in the patch falls below a desired level.

95. A method according to claim 91:

wherein said dispensing further comprises dispensing a second substance from the dispenser to the patch; and

the method further comprises mixing the bioactive composition with dispensing.

96. A method according to claim 95 wherein said mixing occurs between said orifice and said patch.

97. A method according to claim 95 wherein said mixing occurs within said patch.

98. A method according to 91 further comprising containing said bioactive composition with a container portion of said inkjet dispenser prior to said dispensing.

99. A method according to claim 98 further comprising refilling said container portion with said bioactive composition.

100. A method according to claim 99 further comprising removing said container portion from the inkjet dispenser prior to said refilling, and after said refilling, replacing said container portion for further dispensing.

102. A method according to claim 83, wherein said dispensing comprises using a thermal droplet jet dispenser.

103. A method according to claim 83, wherein said dispensing comprises using a piezoelectric droplet jet dispenser.

104. A method according to claim 83, wherein said dispensing comprises using a silicon electrostatic actuated droplet jet dispenser.

105. A method according to claim 91, wherein said inkjet dispenser used in said dispensing comprises a thermal inkjet dispenser,

wherein dispensing the bioactive composition from the thermal inkjet dispenser comprises

receiving the bioactive composition into a feed chamber from a reservoir in the dispenser;

flowing the bioactive composition from the feed chamber into a vaporization chamber in the dispenser;

energizing a firing resistor in the vaporization chamber; and

ejecting the bioactive composition as a droplet from the vaporization chamber.

106. A method according to claim 91, wherein said inkjet dispenser used in said dispensing comprises a piezoelectric inkjet dispenser,

wherein dispensing the bioactive composition from the piezoelectric inkjet dispenser comprises

receiving the bioactive composition into a piezoelectric chamber from a storage chamber in the dispenser;

passing an electric current through a piezoelectric member in the chamber, thereby expanding the piezoelectric member; and

expelling the bioactive composition as a droplet from the vaporization chamber.

107. A method according to claim 91, wherein said inkjet dispenser used in said dispensing comprises a silicon electrostatic actuated inkjet dispenser.

108. A method according to claim 83, further comprising:

optically reading subject identification information with an optical reading device of said jet dispenser;

correlating said subject identification information with prescribed dosage information; and

wherein said dispensing comprises dispensing the bioactive composition according to said prescribed dosage information.

109. A method according to claim 91, further comprising:

optically reading subject identification information with an optical reading device of said inkjet dispenser;

correlating said subject identification information with prescribed dosage information; and

wherein said dispensing comprises dispensing the bioactive composition according to said prescribed dosage information.

118. A method according to claim 83, further comprising:

monitoring a physical parameter of the subject; and

in response to said monitoring, adjusting said dispensing.

119. A method according to claim 118, wherein said physical parameter comprises heartbeats.

120. A method according to claim 118, wherein said physical parameter comprises breathing.

123. A method according to claim 118, wherein said monitoring comprises using a monitor portion of the jet dispenser.

124. A method according to claim 123, wherein said monitor portion comprises a mechanical sensor.

125. A method according to claim 124, wherein said mechanical sensor comprises an accelerometer.

126. A method according to claim 91, further comprising:

monitoring a physical parameter of the subject; and

in response to said monitoring, adjusting said dispensing.

127. A method according to claim 126, wherein said physical parameter comprises heartbeats.

128. A method according to claim 126, wherein said physical parameter comprises breathing.

131. A method according to claim 126, wherein said monitoring comprises using a monitor portion of the jet dispenser.

132. A method according to claim 131, wherein said monitor portion comprises a mechanical sensor.

133. A method according to claim 132, wherein said mechanical sensor comprises an accelerometer.

136. A method according to claim 83, further comprising:

applying a bioactive composition attracting agent to a treatment location on the cutaneous surface of the subject;

pulling the bioactive composition toward said agent; and

penetrating said agent with the bioactive composition to treat the treatment location with the bioactive composition.

140. A method according to claim 83, further comprising manually triggering an activation device after said applying and before said dispensing, with said dispensing occurring in response to said triggering.

141. A method according to claim 91, further comprising manually triggering an activation device after said applying and before said dispensing, with said dispensing occurring in response to said triggering.

148. A method according to claim 83, further comprising:

storing the bioactive composition in a collapsible bladder; and

conveying the bioactive composition from the collapsible bladder to the jet dispenser.

149. A method according to claim 148 wherein said conveying comprises conveying the bioactive composition through tubing.

150. A method according to claim 91, further comprising:

storing the bioactive composition in a collapsible bladder; and

conveying the bioactive composition from the collapsible bladder to the inkjet dispenser through tubing.

183. The method according to claim 83, wherein dispensing is performed with the orifice spaced from and directly above the cutaneous surface or the dermal patch that the bioactive composition will contact.

184. The method according to claim 91, wherein dispensing is performed such that the bioactive composition becomes airborne upon leaving the orifice and remains airborne until the bioactive composition comes into contact with the patch.

185. The method according to claim 91, wherein dispensing includes dispensing the bioactive composition as droplets that travel from the orifice to the patch across an air gap that extends directly from the orifice to the patch.

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IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Appeal Brief-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on August 18, 2008.

Theresa Belland